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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,122	04/22/2004	Robert A. Rousseau	ETH-5126	9010
27777	7590	02/12/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ARAJ, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3733	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/830,122	ROUSSEAU ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Michael J. Araj	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 15 and 16 is/are allowed.
- 6) Claim(s) 1-14 and 17-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/22/04</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 25a and 21a. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,10 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabbay (U.S. Patent No. 4,279,248).

Gabbay discloses a sternal closure device comprising at least one first bearing member (10'), one second bearing member (10), one sternum joining member (20) engaging the first and second bearing members and the at least one sternum joining member adapted to traverse the exposed cancellous surfaces at the sternal incision margins (6) of the first and second portions and begin composed of stainless steel. The sternum joining member, that is arcuate, is comprised an axis, a first end, and a second end, wherein the first end is connected to the first bearing member and the second bearing member is adapted to engage the second end of the sternum joining member. Gabbay also discloses a plurality of sternum joining member connected to a plurality of first bearing member that are connected via a flexible member (see Fig. 4). The sternum joining member is considered flexible because it is expandable with respect to the first and second bearing members allowing for different spacing with various patients and/or locations. The first and second bearing members comprises a sternum contacting surface, a protrusion having a first end and a second end wherein the first end of the protrusion is attached to the sternum contacting surface and wherein the second end of the protrusion is engaged with the sternum joining member (see Figure 1 below). The sternum joining member perpendicularly transverses the exposed cancellous surfaces at the sternal incision margins of the first and second sternal portions.

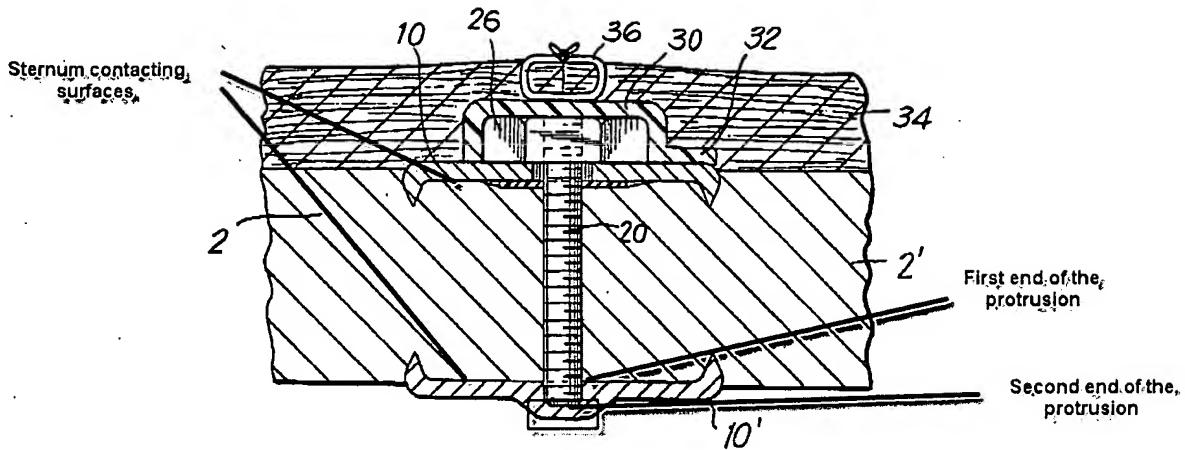


Figure 1 (Altered from Gabbay '248 Fig. 3)

Gabbay also discloses a kit to create and guide hole into the sternum comprising a drill as well as a grasping device (24).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (U.S. Patent No. 4,279,248) in view of Hogendijk et al. (U.S. Patent No. 6,051,007).

Gabbay discloses the claimed invention except for using a securing means that consists of a ratchet or ratchet type surface. Hogendijk discloses a ratchet mechanism so that the dimensions between the opposed clam members can be adjustably selected

to fit a particular patient (Col. 6, paragraph 2). It would have been obvious to one skilled in the art at the time the invention was made to have made the sternum joining member of Gabbay with a ratchet mechanism in view of Hogendijk et al. in order to have an alternate way to adjustably fit the device to the patient.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (U.S. Patent No. 4,279,248) in view of Michelson (U.S. Patent No. 7,094,239).

Gabbay discloses the claimed invention except for the device parts to be coated with a material containing at least one therapeutic agent such as antibiotics, the device parts to be made of a polymer selected from a group such as polyethylene, or using nitinol. Michelson discloses having a screw coated with biologically active chemical agents including but not limited to antibiotics for promoting bone formation (Col. 12, lines 59-65). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Gabbay with a coating of a therapeutic agent in view of Michelson, in order to have a device the will increase bone formation. With respect to claims 11 and 12, it would have been obvious to one having ordinary skill in the art at the time the invention was made to the device using a polyethylene or nitinol, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

***Allowable Subject Matter***

Claims 15 and 16 are allowed.

***Conclusion***

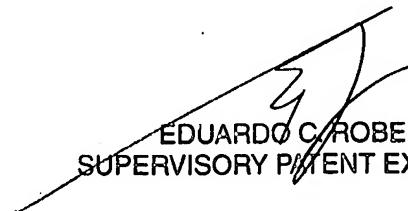
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MJA

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER